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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Mehran Bashiri, Michael Davis
Application No.:	09/944668
Filed:	August 31, 2001
For:	HYBRID BALLOON EXPANDABLE/SELF-EXPANDING STENT
Examiner:	Jessica R. Baxter
Group Art Unit:	3732
Firm Docket No.:	S63.2B-9867-US01

DATE: August 17, 2006TIME: 2:34 P.M.FACSIMILE NO.: 571-273-8300TOTAL NUMBER OF PAGES (including transmittal letter): 12

## FACSIMILE TRANSMITTAL LETTER

Following please find a(n) 11 page Appeal Brief; and 1 page Facsimile Transmittal Letter.

With respect to fees:

- ☐ No additional fee is believed to be required
- ☒ Charge Deposit Account No. 22-0350 in the amount of \$500.00 (Appeal Brief)
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If any extension of time for the accompanying response is required or if a petition for any other matter is required, applicant requests that this be considered a petition therefore.

If any additional fees associated with this communication are required and have not otherwise been paid, please charge the additional fees to Deposit Account No. 22-0350. Please credit overpayment associated with this communication to the Deposit Account No. 22-0350.

Respectfully submitted,  
VIDAS, ARRETT & STEINKRAUS

Date: August 17, 2006By: Brendan C. Babcock

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Heidi J. Steuter

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Docket No.: S63.2-9867-US01

**BRIEF ON APPEAL**

This is a Brief on Appeal for the above-identified application in which claims 1-4, 6-15, 30, and 33-40 were finally rejected in a Final Office Action mailed May 4, 2006. A Notice of Appeal was filed in this case on July 17, 2006. This brief is submitted in accordance with 37 C.F.R. § 41.37:

(a)(1) Appellant must file a brief under this section within two months from the date of filing the notice of appeal under §41.31.

(2) The brief must be accompanied by the fee set forth in §41.20(b)(2).

(b) On failure to file the brief, accompanied by the requisite fee, within the period specified in paragraph (a) of this section, the appeal will stand dismissed.

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal Letter.

(c)(1) The brief shall contain the following items under appropriate headings and in the order indicated in paragraphs (c)(1)(i) through (c)(1)(x) of this section, except that a brief filed by an appellant who is not represented by a registered practitioner need only substantially comply with paragraphs (c)(1)(i) through (c)(1)(iv) and (c)(1)(vii) through (c)(1)(x) of this section:

**(i) Real Party in Interest**

(i) Real party in interest. A statement identifying by name the real party in interest.

The application is assigned to Boston Scientific Scimed, Inc., (former name: Scimed Life Systems, Inc.), One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota corporation. 08/18/2006 MBINAS 00000032 220330 09944668

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Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place,  
Natick, Massachusetts, 01760-1537, a Delaware Corporation.

**(ii) Related Appeals and Interferences**

*(ii) Related appeals and interferences. A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.*

No related appeals or interferences are pending.

**(iii) Status of claims**

*(iii) Status of claims. A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.*

Claims 1-45 are pending. Of these, claims 5, 16-29, 31, 32, and 43 have been withdrawn. Claims 41, 42, 44, and 45 have been allowed. The claims having been rejected and which are being appealed are 1-4, 6-15, 30, and 33-40.

**(iv) Status of amendments**

*(iv) Status of amendments. A statement of the status of any amendment filed subsequent to final rejection.*

No amendment was filed subsequent to the final rejection of May 4, 2006.

**(v) Summary of claimed subject matter**

*(v) Summary of claimed subject matter. A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.*

Independent claims 1, 30, and 38 pertain to a stents having frangible members.  
The required references to the specification and drawings are provided in brackets in the claim summaries below.

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According to independent claim 1, a stent having a longitudinal axis comprising a non-woven tubular element having a plurality of openings therein is provided [p. 6, lns. 10-13; see 111 of Fig. 1]. The tubular element comprises a plurality of interconnected struts which form at least one continuous pathway which extends all the way around the longitudinal axis [p. 6, lns. 10-13; Fig. 1]. The interconnected struts have an outside surface facing outside the stent and an inner surface facing the longitudinal axis, and a side portion there between; the side portion having a thickness defined by the radial distance between the outer surface and the inner surface [p. 10, lns. 22-25; see 121 and 123 of Fig. 9]. The stent further comprises at least one of the struts being a frangible temporary strut [p. 3, lns. 1-2]. The frangible temporary strut restrains at least two of the interconnected struts from self-expansion wherein at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one frangible temporary strut [p. 6, lns. 16-18]. The thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut [p. 9, lns. 7-9; see 114 vs 112 of Fig. 9].

According to independent claim 30, a stent having a longitudinal axis comprising a generally non-woven tubular body having interconnected struts which form at least one continuous pathway which extends around the longitudinal axis is provided [p. 6, lns. 10-13; Fig. 1]. The interconnected struts have an outside surface facing outside the stent and an inner surface facing the longitudinal axis, and a side portion there between; the side portion having a thickness defined by the radial distance between the outer surface and the inner surface [p. 10, lns. 22-25; see 121 and 123 of Fig. 9]. The stent further comprises at least one frangible temporary strut disposed completely between at least two interconnected struts and restraining the interconnected struts from self-expansion [p. 2, lns 18-21]. At least a portion of the stent is capable of self-expanding upon breaking of the frangible temporary strut [p. 6, lns. 16-18]. The frangible temporary strut is at least partially constructed from metal [p. 8, lns. 14-17]. The thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut [p. 9, lns. 7-9; see 114 vs 112 of Fig. 9].

According to independent claim 38, a non-woven stent formed of a plurality of interconnected struts and having a longitudinal axis is provided [p. 6, lns. 10-13]. The

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interconnected struts have an outside surface facing outside the stent and an inner surface facing the longitudinal axis, and a side portion there between; the side portion having a thickness defined by the radial distance between the outer surface and the inner surface [p. 10, lns. 22-25; see 121 and 123 of Fig. 9]. The interconnected struts include at least one temporary strut and permanent struts wherein the permanent struts fully defining at least one opening in the stent [p. 6, lns. 11-16; see 11 and 112 of Fig. 1]. The at least one temporary strut restrains self-expansion of at least one permanent strut about the at least one opening, and the at least one temporary strut but not the permanent struts breaks upon the application of a predetermined outward pressure to the stent [p. 2, lns. 20-26]. The thickness of a portion of the temporary strut being substantially narrower than the thickness of any other portion of the temporary strut [p. 10, lns. 19-20; Fig. 9]. At least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one temporary strut [p. 2, lns. 25-26]. No portion of the temporary strut overlaps any portion of the outer surface of the permanent struts being restrained [p. 2, lns. 20-21]. The pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof [p. 4, lns. 8-9].

**(vi) Grounds of Rejection to be Reviewed on Appeal**

*(vi) Grounds of rejection to be reviewed on appeal. A concise statement of each ground of rejection presented for review.*

Review on appeal is requested of the Examiner's contention that claims 1-4, 6-10, 14, 15, 30, 33, 34, and 38 are anticipated by PG-PUB 2002/0107560 to Richter.

Review on appeal is also requested of the Examiner's contention that claims 11-13, 35-37, 39, and 40 are obvious from Richter '560 in view of Lock et al. (U.S. 5,591,223).

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**(vii) Argument**

(vii) *Argument.* The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to §41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.

**1. The Examiner Erred in rejecting claims 1-4, 6-10, 14, 15, 30, 33, 34, and 38 are anticipated by PG-PUB 2002/0107560 to Richter.**

Claims 1-4, 6-10, 14, 15, 30, 33, 34, and 38 have been rejected under 35 USC 102(e) by PG-PUB 2002/0107560 to Richter. The rejection must be reversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131. The Examiner has not made the requisite showing.

Claims 1, 30, and 38 all require restraining self-expansion of at least a portion of the stent. In regard to this limitation the Examiner points to paragraph 0009 of Richter. However, neither this paragraph nor the remainder of the Richter application teach restraining *self-expansion* of the interconnected struts or stent.

In fact, Richter teaches detachment struts that allow the stent to detach into multiple stent segments after stent expansion (paragraph 0006 of Richter). This detachment is caused by "physiological stress" placed on the detachment struts. This physiological stress is caused by body functions of the patient (i.e. motion of the treated vessel). In addition, this breaking of the detachment struts occurs after implantation of the stent; in some instances after such a time that the segments are buried under neointima (paragraph 0008 of Richter). Thus, in the Richter reference the stent is first expanded and then the detachment struts are broken.

This is in stark contrast to independent claims 1, 30, and 38 which recite as follows:

;

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Claim 1: "at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one frangible temporary strut";

Claim 30: "at least a portion of the stent capable of self-expanding upon breaking of the frangible temporary strut";

Claim 38: "at least a portion of the stent capable of self-expanding upon breaking of the temporary strut".

The instant claims teach self-expansion upon breaking of a strut or in some instances multiple struts. Richter fails to teach self-expansion and further fails to teach self-expansion upon breaking a strut. Thus, Richter does not teach all the limitations of the instant claims.

For at least these reasons, reversal of the rejection under 35 USC §102(e) is respectfully requested.

**2. The Examiner Erred in rejecting claims 11-13, 35-37, 39, and 40 are obvious from Richter '560 in view of Lock et al. (U.S. 5,591,223)**

Claims 11-13, 35-37, 39, and 40 have been rejected under 35 USC 103 as obvious from Richter '560 in view of Lock et al. (U.S. 5,591,223).

As stated in MPEP 2143 and throughout the caselaw, "the prior art reference (or references when combined) must teach or suggest all the claim limitations."

These claims are dependent upon independent claims 1, 30, and 38. As stated above Richter does not teach the limitations of claims 1, 30, and 38. The stent of Lock is designed to allow for a second possible dilation of the stent. Pediatric patients who have had a stent implanted may need to have the stent further dilated as their lumens grow. Thus, the breakable members of Lock can be broken in order to further expand the stent. However, there is no teaching or suggestion in Lock regarding struts restraining *self-expansion* as taught in independent claims 1, 30, and 38. As stated above, Richter also fails to teach or suggest this limitation.

Therefore, even if Richter and Lock were combined in the manner proposed, the resulting hybrid would fail to teach or suggest all of the elements of the instant claims.

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For at least this reason, claims 11-13, 35-37, 39, and 40 are allowable as they claim dependence upon independent claims 1, 30, and 38 which are believed to be in condition for allowance. Applicant respectfully requests that the 103(a) rejection be withdrawn.

**3. Conclusion**

The Examiner has failed to provide a teaching or suggestion of all the limitations of independent claims 1, 30, and 38. Thus, claims 1-4, 6-15, 30, and 33-40 are in condition for allowance. The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: August 17, 2006

By: 

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**(viii) Claims Appendix**

*(viii) Claims appendix. An appendix containing a copy of the claims involved in the appeal.*

**Claim 1. (Previously Presented)** A stent having a longitudinal axis comprising:  
a non-woven tubular element having a plurality of openings therein, the tubular element comprising a plurality of interconnected struts which form at least one continuous pathway which extends all the way around the longitudinal axis, the interconnected struts having an outside surface facing outside the stent, an inner surface facing the longitudinal axis, and a side portion there between, the side portion having a thickness defined by the radial distance between the outer surface and the inner surface; the stent further comprising at least one of the struts being a frangible temporary strut, the frangible temporary strut restraining at least two of the interconnected struts from self-expansion, at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one frangible temporary strut, the thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut.

**Claim 2. (Previously Presented)** The stent of claim 1 wherein the portion of the stent which is constructed and arranged to self-expand upon breaking of the frangible temporary strut is made of a shape-memory material.

**Claim 3. (Original)** The stent of claim 2 wherein the shape memory material is from the group consisting of shape-memory metals and shape-memory plastics.

**Claim 4. (Previously Presented)** The stent of claim 1 wherein the entirety of the stent is constructed and arranged to self-expand upon breaking of the frangible temporary strut.

**Claim 6. (Previously Presented)** The stent of claim 1 wherein the frangible temporary strut is constructed from a different material than the interconnected struts.

**Claim 7. (Previously Presented)** The stent of claim 1 comprising a plurality of frangible temporary struts, each of which extends between at least two adjacent interconnected-struts.

**Claim 8. (Previously Presented)** The stent of claim 7 wherein the frangible temporary struts are selected from at least one member of the group consisting of: frangible welds, frangible glues, frangible solder, and any combination thereof.

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Claim 9. (Previously Presented) The stent of claim 7 wherein the frangible temporary struts are distributed uniformly throughout the stent.

Claim 10. (Previously Presented) The stent of claim 7 wherein the frangible temporary struts are distributed about at least one end of the stent.

Claim 11. (Previously Presented) The stent of claim 7 wherein the stent is capable of withstanding an outward pressure of up to 2 atmospheres without breakage of the frangible temporary struts, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 12. (Previously Presented) The stent of claim 7 wherein the stent is capable of withstanding an outward pressure of up to 5 atmospheres without breakage of the frangible temporary struts, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 13. (Previously Presented) The stent of claim 7 wherein the stent is capable of withstanding an outward pressure of up to 12 atmospheres without breakage of the frangible temporary struts, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 14. (Previously Presented) The stent of claim 1 wherein the frangible temporary strut includes a circumferential extending component.

Claim 15. (Previously Presented) The stent of claim 1 wherein the frangible temporary strut includes a curved portion.

Claim 30. (Previously Presented) A stent having a longitudinal axis comprising a generally non-woven tubular body having interconnected struts which form at least one continuous pathway which extends around the longitudinal axis, the interconnected struts having an outside surface facing outside the stent, an inner surface facing the longitudinal axis, and a side portion there between, the side portion having a thickness defined by the radial distance between the outer surface and the inner surface; the stent further comprising at least one frangible temporary strut disposed completely between at least two interconnected struts and restraining the interconnected struts from self-expansion, at least a portion of the stent capable of self-expanding upon breaking of the frangible temporary strut, the frangible temporary strut at least partially

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constructed from metal, the thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut.

Claim 33. (Previously Presented) The stent of claim 30 comprising a plurality of frangible temporary struts.

Claim 34. (Previously Presented) The stent of claim 30 where the entirety of the stent is capable of self-expanding upon breaking of the frangible temporary strut.

Claim 35. (Previously Presented) The stent of claim 30 wherein the stent is capable of withstanding outward pressures of up to 2 atmospheres without breakage of the frangible temporary strut, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 36. (Previously Presented) The stent of claim 30 wherein the stent is capable of withstanding outward pressures of up to 5 atmospheres without breakage of the frangible temporary strut, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 37. (Previously Presented) The stent of claim 30 wherein the stent is capable of withstanding outward pressures of up to 12 atmospheres without breakage of the frangible temporary strut, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 38. (Previously Presented) A non-woven stent formed of a plurality of interconnected struts and having a longitudinal axis, the interconnected struts having an outside surface facing outside the stent, an inner surface facing the longitudinal axis, and a side portion there between, the side portion having a thickness defined by the radial distance between the outer surface and the inner surface, the interconnected struts including at least one temporary strut and permanent struts, the permanent struts fully defining at least one opening in the stent, the at least one temporary strut restraining self-expansion of at least one permanent strut about the at least one opening, the at least one temporary strut but not the permanent struts breaking upon the application of a predetermined outward pressure to the stent, the thickness of a portion of the temporary strut being substantially narrower than the thickness of any other portion of the temporary strut, at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one temporary strut, no portion of the temporary strut overlapping any

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portion of the outer surface of the permanent struts being restrained the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 39. (Previously Presented) The stent of claim 38 wherein the predetermined outward pressure is in excess of 2 atmospheres.

Claim 40. (Previously Presented) The stent of claim 38 wherein the predetermined outward pressure is in excess of 12 atmospheres.

*(ix) Evidence appendix. An appendix containing copies of any evidence submitted pursuant to §§1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See §41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.*

Not applicable

*(x) Related proceedings appendix. An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.*

Not applicable

*(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See §1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and §41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.*

*(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.*

*(e) The time periods set forth in this section are extendable under the provisions of §1.136 of this title for patent applications and §1.550(c) of this title for ex parte reexamination proceedings.*